DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 4, 2015

Smith & Nephew, Inc.
Mr. Samir Ibrahim
Senior Regulatory Affairs Specialist
150 Minuteman Rd.
Andover, Massachusetts 01810

Re: K143172
Trade/Device Name: ACL Smart System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI, MBI
Dated: November 3, 2014
Received: November 4, 2014

Dear Mr. Ibrahim,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): __K143172_____

Device Name: **ACL SMART System**

Indications for Use:

The Smith & Nephew ACL SMART System is indicated for fixation of soft tissue grafts during cruciate ligament reconstruction.

Prescription Use __X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801.109) (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

_____
(Division Sign Off)
Division of Orthopedic Devices
510(k) Number: K142933

510(k) Summary
Smith & Nephew, Inc. ACL SMART System

Submitted by:	Smith & Nephew, Inc. 150 Minuteman Road Andover, MA 01810
Date of Summary:	January 23, 2015
Contact Person and Address:	Samir Ibrahim, PhD, MBA, RAC Senior Regulatory Affairs Specialist T (901) 399-6139 F (901) 721-2421
Name of Device(s):	Smith & Nephew, Inc. ACL SMART System
Common Names:	Fastener, Fixation, Biodegradable, Soft Tissue Fastener, Fixation, Nondegradable, Soft Tissue
Device Classification Names and References:	21 CFR 888.3030 Single/multiple component metallic bone fixation and accessories.
Device Class:	Class II
Panel Code:	Orthopedics
Product Codes:	MAI (primary) MBI (secondary)

Device Description

The subject device combines two cleared devices (i.e., EndoButton CL Ultra and GTS Tapered Screw) into disposable kits along with the necessary disposable instruments to perform cruciate ligament reconstruction procedures. Both the EndoButton CL Ultra and GTS Tapered Screw provided in the ACL SMART System are identical in design to the previously cleared predicate devices. However, the GTS Tapered Screw was originally cleared for use with the GTS Sleeve and the GTS Tapered Screw in the ACL SMART System is intended to be used independent of the sleeve.

Indications for Use

The Smith & Nephew ACL SMART System is indicated for fixation of soft tissue grafts during cruciate ligament reconstruction.

The indications for the subject device are identical to the GTS Tapered Screw and similar to the EndoButton CL Ultra and BioRCI Screw. The indications of the EndoButton CL Ultra and BioRCI Screw also include fixation of soft tissue grafts during cruciate ligament reconstruction, therefore the indications of the subject device are equivalent to the predicate devices.

Technological Characteristics

Device comparisons described in this premarket notification demonstrate that the proposed implants in the ACL SMART System are substantially equivalent to the legally marketed predicate devices (listed below in Table 1) with regard to indications for use and performance characteristics. The primary technological differences that exist between the subject and predicate implant devices are the following:

- Use of the GTS Tapered Screw without the GTS Sleeve.

Table 1: Substantially Equivalent Predicates to the implants in the ACL SMART System

Manufacturer	Description	Submission Number	Clearance Date
Smith & Nephew, Inc.	EndoButton CL Ultra	K980155, K081098	04/01/1998
Smith & Nephew, Inc.	GTS Sleeve and GTS Tapered Screw	K040542	03/25/2011
Smith & Nephew, Inc.	BioRCI Screw	K992396, K032224	10/07/2004

Summary of Preclinical Testing

To further support a determination of substantial equivalence, non-clinical bench (mechanical) testing was conducted on the GTS Tapered Screw without the GTS sleeve. Test results demonstrated that the proposed device is substantially equivalent to the previously cleared BioRCI Screw predicate device listed in Table 1. The specific types of non-clinical testing conducted are listed below:

- Fixation strength
- Insertion

Conclusion

Based on the similarities to the predicate devices and a review of the mechanical testing performed, the subject device is substantially equivalent to the predicate devices listed in Table 1.